

EXHIBIT 1

Appl. No. 10/534,978
Reply to Office Action of October 30, 2007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/534,978
Applicant : Zhuangwu Li, et al.
Filed : November 9, 2005
Title : METHODS AND COMPOSITIONS FOR DETECTING
TELOMERASE ACTIVITY
TC/A.U. : 1637
Examiner : Thomas, David.
Docket No. : 159976
Customer No. : 038598

Mail Stop AF
Commissioner of Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

DECLARATION OF DR. ZHUANGWU LI UNDER 37 C.F.R. § 1.132

I, Zhuangwu Li, do hereby declare as follows:

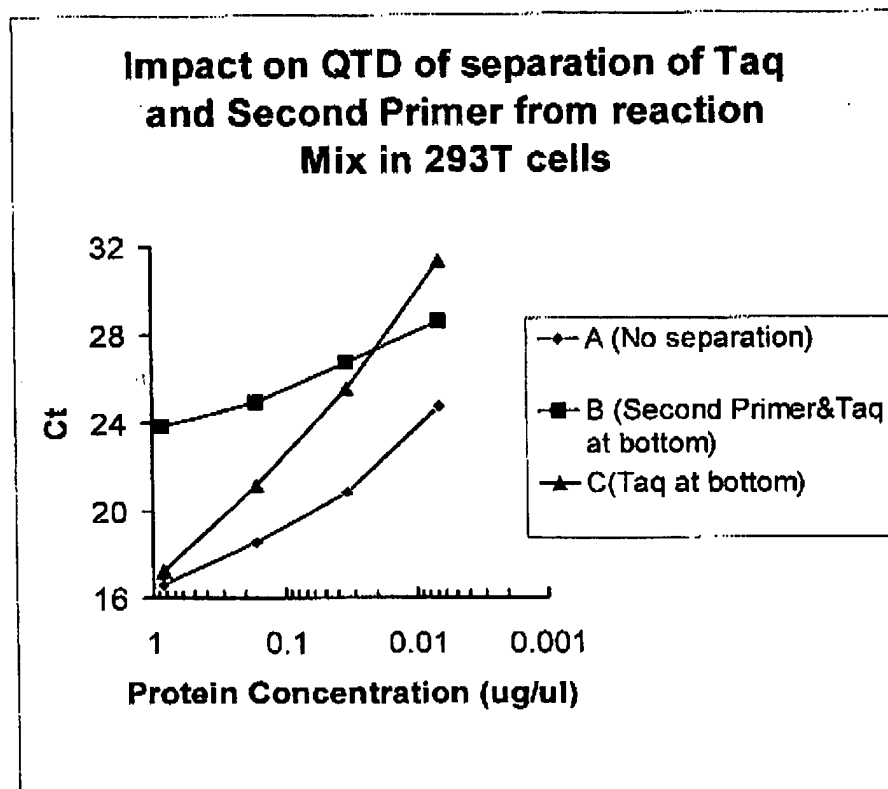
1. I am the first named inventor of the above-identified patent application.
2. I have over fifteen years of experience in biomedical research and product development. I currently hold the position of Chief Executive Officer at Allied Biotech, Inc. in Ijamsville, Maryland.
3. The above-identified patent application is directed to an assay method for detecting and quantifying telomerase activity in a biological sample. The assay involves two key reactions, a telomerase extension reaction and a polymerase chain reaction (PCR) to amplify the telomerase extension product.

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4. We discovered, through extensive experimentation, that high specificity is achieved by separating the PCR reaction from the telomerase extension reaction. Specifically, the two reactions are separated by using a reaction tube containing a first reaction mixture containing a first primer for telomerase extension and nucleoside triphosphates; a second reaction mixture containing a second primer for PCR amplification and a DNA polymerase; and a wax layer separating the first reaction mixture from the second reaction mixture.

5. As shown in the figure shown below, compared to the control reactions, the threshold cycle (Ct) for detection increases when both the second primer and the DNA polymerase (Taq) are placed under the wax. The increased threshold cycles result in higher specificity.



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10. I declare that all statements made herein based on my own knowledge are true, and that all statements made herein based on information and belief are believed to be true. I further declare that these statements are made with the knowledge that willful false statements are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United State Code, and that willful false statements may jeopardize the validity of the above-referenced patent application and any patent that issues therefrom.

12/18/2007

Date:



Dr. Zhuangwu Li